

REMARKS

I. THE STATUS OF THE CLAIMS

Claims 1-6, 8-19, 21 and 23-25 are pending in the application. Claims 1-6, 8-17, 19, 21 and 23-25 are rejected. Claim 18 is withdrawn from consideration.

Claims 1 and 19 are amended; claim 22 is canceled; and claims 25 and 26 are added. Support for the amendment can be found in the specification at, for example, paragraph [0076] and paragraph [0083].

II. THE REJECTIONS UNDER 35 U.S.C. § 103

The Office Action rejects claims 1-6, 8-17, 19, 21-25 under 35 U.S.C. § 103 as being obvious over Gowan (U.S. Patent No. 5,374,659), Gergely et al. (U.S. Patent No. 5,834,019), Patel et al. (U.S. Patent No. 6,569,463), Eichman (U.S. Patent No. 5,980,882), McNamara et al. (U.S. Patent No. 6,423,298), Hagemann et al. (U.S. Patent No. 5,211,957) and Saeedi et al. (Prevention of Crystal Growth in Acetaminophen Suspensions by the Use of Polyvinyl Pyrrolidone Bovine Serum Albumin; DARU, Volume 11, Number 3 (2003)). In particular, the Office Action asserts:

It would have been obvious to one of ordinary skill in the art to combine the teachings of Gowan, Jr., Gergely et al., Patel et al., Eichman and Hagemann et al. The motivation to combine the teachings is because (1) Gowan, Jr. teaches an aqueous pharmaceutical suspension composition comprising an insoluble pharmaceutical active, a suspension stabilizing effective amount of xanthan gum (hydrocolloid and thickener), pregelatinized starch (swelling agent and thickener) and polyoxyethylene sorbitan monooleate (surfactant) (see abstract). Application of the compositions and method of the present invention for medical and pharmaceutical uses can be accomplished by any clinical, medical and pharmaceutical methods and techniques as are presently or prospectively known to those skilled in the art. Thus it is intended that the present invention cover the modifications and variations of this invention provided that they come within the scope of the appended claims and their equivalents (col 7 lines 54-61); (2) Gergely et al. teaches [l]oratadine is virtually completely water-insoluble and has a very strongly hydrophobic character. It is thus extremely poorly wettable and therefore difficult to suspend. Its fine particles furthermore have the tendency to form a film on the water surface, to creep up the glass wall to a pronounced extent and to adhere relatively strongly there[;] (3) Patel et al.[.] teaches solubilizers for use in the compositions include triacetin, triethylcitrate, ethyl oleate, ethyl caprylate, dimethylacetamide, N-methylpyrrolidone, N-hydroxyethylpyrrolidone, polyvinylpyrrolidone (nucleation inhibitor) ([c]ol 29 line[s] 57-60). Other additives include enzyme inhibitors and chelating agents such as EDTA[;] (4) Eichman teaches drug resin complexes stabilized by chelating agents. "The particle size of a resin can differ between two resins." The chelating agent is preferably EDTA (amino polycarboxylic acid compound). EDTA is known to stabilize drugs in solution by retarding their oxidation [(]col 2 lines 60-61)[;] and (5) Hagemann et al. teaches [that] pharmaceutically

acceptable excipients are, in particular[,] viscosity index improvers which are suitable for stabilizing aqueous suspensions and which inhibit sedimentation include PVP (col 4 lines 42-65). A skilled artisan would have reasonable expectation of effectively stabilizing loratidine (antihistamine) a water-insoluble pharmaceutical active.

Applicants respectfully traverse the rejection.

Applicants submit that in addition to the reasons provided in the Amendment filed on February 5, 2010, neither Gowan, Gergely et al., Patel et al., Eichman, nor Hagemann et al. disclose the use of **from above about 0 to about 5 % weight per volume polyvinylpyrrolidone** as a nucleation inhibitor *and* the use of **from about 0.005 to about 0.1 % weight per volume of an amino polycarboxylic acid compound** to impart improved pH and viscosity stability in a pharmaceutical composition.

In addition, newly cited McNamara et al., which discloses that EDTA may be employed as a stabilizer, and newly cited Saeedi et al., which discloses the use of polyvinylpyrrolidone and bovine serum albumin as crystal growth inhibitors of acetaminophen, also do not disclose or suggest the claimed invention. Reconsideration and withdrawal of the rejection of claims 1-6, 8-17, 19 and 21-25 under 35 U.S.C. § 103 over Gowan, Gergely et al., Patel et al., Eichman, McNamara et al., Hagemann et al. and Saeedi et al. are respectfully requested.

The Office Action rejects claims 1-6, 8-17, 19 and 21-25 under 35 U.S.C. § 103 as being obvious over Reinhardt et al. (U.S. Patent No. 6,217,998) in view of Hansenne et al. (U.S. Patent No. 6,916,464), Walch (U.S. Patent No. 6,790,847) and Patel et al. (U.S. Patent No. 6,569,463). In particular, the Office Action asserts:

[A] skilled artisan would have a reasonable expectation of successfully producing a topical formulation with a local antihistamine effect with the pH claimed. The motivation comes from the teaching of Walch that the antihistamine loratidine is useful for topical application; the composition is incorporated with cosmetics inclusive of pigments; and Hansenne et al. [which discloses that] a pH which is compatible with the skin preferably ranging from 3 to 9 and better still from 3.5 to 7.5. Hence, a skilled artisan would have had reasonable expectation of successfully producing a composition with similar efficacy and results.

Applicants respectfully traverse the rejection.

Applicants submit that neither Reinhardt et al., which discloses a liquid makeup composition that is absorbed on and absorbent material and dried, Hansenne et al, which discloses sunscreen compositions, Walch, which discloses a drug composition containing loratidine and excipients, nor Patel et al., which was discussed previously, disclose the use of **from above about 0 to about 5 % weight per volume polyvinylpyrrolidone** as a nucleation inhibitor *and* the use of **from about 0.005 to about 0.1 % weight per volume of an amino polycarboxylic acid compound** to impart improved pH and viscosity stability in a pharmaceutical composition.

Reconsideration and withdrawal of the rejection of claims 1-6, 8-17 and 19, 21-25 under 35 U.S.C. § 103 over Reinhardt et al. in view of Hansenne et al., Walch and Patel et al. are respectfully requested.

III. Conclusion

Early consideration and prompt allowance of the claims are respectfully requested. If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5017US/LAD.

Respectfully submitted,

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